

REMARKS

This responds to the Final Office Action dated March 17, 2004.

No claims are amended, canceled or are added; as a result, claims 16-46 are now pending in this application.

Objection to the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subjected matter. Applicant has amended the specification. No new matter is introduced by the amendments. Support for the amendments is found, for example, in Figures 1 and 9-14.

Withdrawal of the objection to the specification is respectfully requested.

§103 Rejection of the Claims

Claims 16-20, 24, 26, 43, 45 and 46 were rejected under 35 USC § 103(a) as being unpatentable over Nelson et al. (U.S. Patent No. 6,249,708), hereinafter Nelson.

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

Applicant respectfully traverses the rejections. The rejections of claims 16-20, 24, 26, 43, 45 and 46 fail, among other reasons, because Nelson does not identify a proper motivation to modify the reference in the manner proposed. According to M.P.E.P. § 2143.01, the mere fact that a reference *can* be modified does not render the resultant modification obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of modification. Moreover, according to M.P.E.P. § 2144, “the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art, established scientific principles or legal precedent.” (emphasis added). The Office Action states at page 3, second paragraph, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials . . .

since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead.” Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Nelson would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in claims 17-20, 24, 26, 43, 45 and 46. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

2. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because Nelson Teaches Away From the Claims.

Applicant traverses the rejections of claims 16-20, 24, 26, 43, 45 and 46 because, among other reasons, Nelson teaches away from the proposed modification. According to M.P.E.P. § 2143.03, “Prior art must be considered in its entirety, including disclosures that teach away from the claims.” Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963). Nelson states at column 4, lines 40-45, “Because the catheter lead 10 is preferably constructed of a flexible medical grade silicon rubber material, the ability of the fluted channels 42 to serve as mechanisms for inserting a stiffening material . . . allows for the construction of . . . transition zones (i.e., longitudinal lengths of the lead having different

flexibility characteristics than adjacent regions).” Moreover, Nelson states at column 9, line 66 to column 10, line 1, “a stiffening material [fills] at least a portion of at least one of the plurality of longitudinally-oriented fluted channels that is open and without a conductor.”

Nelson teaches away from the proposed modification because Nelson advises using inserted stiffening material separate from the conductors as opposed to the apparatus recited in claim 16 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

3. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because the Office Action Does Not Consider the Claims as a Whole.

The rejections of claims 16-20, 24, 26, 43, 45 and 46 fail because the rejections do not consider the claims as a whole. Pursuant to M.P.E.P. § 2141.02, “In determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences *themselves* would have been obvious, but whether the claimed inventions *as a whole* would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). For example, the Office Action at page 3, second paragraph states, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with insulated conductors being different materials.” Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejections focus upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established. Additionally, by failing to consider the invention as a whole, the Office Action uses hindsight reconstruction. The teaching or suggestion to make the claimed device must be found in the prior art, not in the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

Reconsideration and allowance of claims 16-20, 24, 26, 43, 45 and 46 are respectfully requested.

Claims 21-23, 25 and 44 were rejected under 35 USC § 103(a) as being unpatentable over Nelson et al. (U.S. Patent No. 6,249,708).

Claims 21-23

Applicant respectfully submits that claims 21-23 are patentable as dependent claims of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claims 21-23.

Reconsideration and allowance of claims 21-23 are respectfully requested.

Claim 25

Applicant respectfully traverses the rejection. The rejection of claim 25 fails, among other reasons, because a proper motivation to modify Nelson in the manner proposed has not been identified. The Office Action states at page 4, third paragraph, “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Nelson, with a conductor having heat setting capabilities since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration.” Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Nelson would be in need of an individually insulated coradial conductors formed of material having heat setting capabilities, as recited in claim 25. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

Applicant also respectfully submits that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

Claim 44

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Nelson.

Applicant respectfully traverses the rejection. The rejection of claim 44 fails, among other reasons, because Nelson does not identify a proper motivation to modify the reference in the manner proposed. Applicant is unaware of a requirement for showing an advantage, use for a particular purpose, or solution of a stated problem. Office Action, page 4, first paragraph. Rather, pursuant to M.P.E.P. § 706.02(j), “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” See also *In Re San Su Lee*, 277 F.3d 1338 (CAFC 2002). Applicant respectfully submits the statement in the Office Action at page 3, last paragraph, “It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Nelson . . . [so the] first conductor [is] disposed only in the second and third sections” is a conclusory statement that does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Further, the Office Action does not state how Nelson would be in need of the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections, as recited in claim 44. Applicant cannot find any objective suggestion in Nelson to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Nelson in the manner proposed or withdraw the rejection.

2. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because Nelson Does Not Teach All the Elements of Claim 44.

Applicant respectfully submits Nelson does not teach all the elements of claim 44, as required by M.P.E.P. § 2143.03. Applicant can find no disclosure, teaching or suggestion in Nelson of, for example, the lead body including a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and third sections, where the first conductor is disposed only in the first and third sections. Further, the Office Action states at page 3, last paragraph, “Nelson discloses the claimed invention but does not disclose expressly . . . the first conductor being disposed only in the second and third sections.”

Applicant respectfully submits, claim 44 recites the first conductor is disposed only in the first and third sections. Pursuant to M.P.E.P. § 2143.03, Applicant respectfully requests the Examiner show in Nelson where teaching or suggestion of the missing element is found.

Moreover, absent such a showing of objective support or objective reasoning, Applicant assumes the Examiner is taking Official Notice of the missing elements. Applicant respectfully submits there appears to be no evidence in the record to support taking Official Notice, and pursuant to M.P.E.P. § 2144.03, requests a reference showing the missing elements.

Alternatively, Applicant submits the assertions made are unsupported by the reference and are within the personal knowledge of the Examiner. Further, the Examiner has stated in the Office Action at page 7, last paragraph, “The Examiner has not made a 103 rejection on common knowledge in the art or ‘well known’ prior art.” Applicant therefore submits the assertions appear to be within the personal knowledge of the Examiner. Applicant requests an Examiner’s affidavit supporting the unsupported assertions pursuant to 37 C.F.R. 1.104(d)(2) and M.P.E.P. § 2144.03.

Reconsideration and allowance of claim 44 are respectfully requested.

Claims 16-20, 24, 43, 45 and 46 were rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 5,935,159), hereinafter Cross.

1. The Office Action Fails to Provide a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Selectively Modify Cross.

Applicant respectfully traverses the rejections. The rejections of claims 16-20, 24, 43, 45 and 46 fail, among other reasons, because Cross does not identify a proper motivation to modify the reference in the manner proposed. Pursuant to M.P.E.P. § 706.02(j), “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” See also *In Re San Su Lee*, 277 F.3d 1338 (CAFC 2002). Applicant respectfully submits that the evidence of record does not appear to identify an objective source for the motivation to modify Cross in the manner proposed. The Office Action states at page 4, last paragraph to page 5, first paragraph, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials . . . since it was known in the art that leads are provided with insulated conductors being different materials, wherein the first material has a different stiffness than a second material to provide . . . different flexibility/stiffness to the lead.” Applicant respectfully submits the statement in the Office Action is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144.

Further, the Office Action does not state how Cross would be in need of individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material, as recited in claim 16 and incorporated in dependent claims 17-20, 24, 43, 45 and 46. Applicant cannot find any objective suggestion in Cross to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Cross in the manner proposed.

2. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because Cross Teaches Away From the Claims.

The rejections of claims 16-20, 24, 43, 45 and 46 fail because, among other reasons, Cross appears to teach away from the proposed modification. Applicant submits Cross states at column 4, lines 40-45, “the core 102a takes the form of multiple sections 150, 152 and 154 which are structurally identical to one another, but are extruded of differing materials. For example, if a change in flexibility is desired along the length of the lead, core members fabricated of polyurethanes of differing hardness may be employed.” Cross teaches away from the proposed modification because Cross advises using extruded sections comprised of differing materials as opposed to the apparatus recited in claim 16 and incorporated in claims 17-20, 24, 43, 45 and 46 having individually insulated coradial conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, wherein the first material has a different stiffness than the second material.

Additionally, Applicant respectfully traverses the statement in the Office Action at page 5, first paragraph, “the first conductor extending from a connector ring to an electrode will provide the claimed limitation of the first conductor only extending over the second section.” Applicant is unaware of such a claimed limitation. Applicant respectfully requests clarification or withdrawal of the statement.

3. The Office Action Fails to Establish a Prima Facie Case of Obviousness Because the Office Action Does Not Consider the Claims as a Whole.

The rejections of claims 16-20, 24, 43, 45 and 46 fail because the rejections do not consider the claims as a whole. M.P.E.P. § 2141.02. For example, the Office Action at page 4, last paragraph to page 5, first paragraph states, “It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with insulated conductors being different materials.” Applicant respectfully submits the Office Action merely states the differences of the claims with respect to the prior art are obvious instead of focusing on the claims as a whole. Because the rejections focus upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been

established. Additionally, by failing to consider the invention as a whole, the Office Action uses hindsight reconstruction. The teaching or suggestion to make the claimed device must be found in the prior art, not in the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2143. The Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

Clarification of the rejections of claims 16-20, 24, 43, 45 and 46 are respectfully requested. Reconsideration and allowance of claims 16-20, 24, 43, 45 and 46 are respectfully requested.

Claims 21-23, 25 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Cross, Jr. et al. (U.S. Patent No. 5,935,159).

Claims 21-23 and 26

Applicant respectfully submits that claims 21-23 and 26 are patentable as dependent claims of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claims 21-23 and 26.

Reconsideration and allowance of claims 21-23 and 26 are respectfully requested.

Claim 25

Applicant respectfully traverses the rejection. The rejection of claim 25 fails, among other reasons, because a proper motivation to modify Cross in the manner proposed has not been identified. The Office Action states at page 6, third paragraph, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Cross, with a conductor having heat setting capabilities . . . since it was known in the art that leads are provided with conductors having heat setting capabilities to allow the lead to be easily shaped into a bias configuration." Applicant respectfully submits the statement is conclusory and does not appear to be reasoned as required by M.P.E.P. § 2144, and therefore does not provide a rationale to modify Nelson in the manner proposed.

Furthermore, the Office Action does not state how Cross would be in need of an individually insulated coradial conductors formed of material having heat setting capabilities, as

recited in claim 25. Applicant cannot find any objective suggestion in Cross to employ such structure. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify Cross in the manner proposed or withdraw the rejection.

Applicant also respectfully submits that claim 25 is patentable as a dependent claim of patentable base claim 16, and the discussion for claim 16 above is repeated in support of claim 25.

Reconsideration and allowance of claim 25 are respectfully requested.

Information Disclosure Statement

Applicant respectfully requests that a copy of the 1449 Form, listing all references that were submitted with the Information Disclosure Statement filed on July 10, 2001, a Supplemental Information Disclosure Statement filed on May 7, 2002 and a Supplemental Information Disclosure Statement filed on July 13, 2001 marked as being considered and initialed by the Examiner, be returned with the next official communication.

Response to Arguments

Applicant is unclear as to the applicability of U.S. Patent Nos. 6,253,111, 4,640,983, 6,400,992, 5,849,032 and 5,052,407 to claims 16-46. The Office Action does not appear to use the references in a fully developed rejection according to M.P.E.P. § 707.07(g). Applicant respectfully traverses the statement in the Office Action at page 6, last paragraph, “The request for prior art that shows it would be obvious to use conductors of different materials having varying stiffness . . . has previously been met.” Pursuant to M.P.E.P. § 707.07(g), “The Examiner should reject each claim on all valid grounds available . . . Where a major technical rejection is proper, it should be stated with a *full development* of reasons rather than by mere conclusion.” (emphasis added). Applicant respectfully submits the Office Action statement at page 6, last paragraph, “The last Office Action provided three teachings . . . that show the use of different conductors having different stiffness,” is conclusory and not fully developed. Pursuant to M.P.E.P. § 707.07(g), Applicant respectfully requests the Examiner provide a fully developed rejection or withdraw this line of argument. Moreover, pursuant to M.P.E.P. § 707.07(g),

Applicant respectfully requests the Examiner provide a fully developed rejection with U.S. Patent Nos. 5,849,032 and 5,052,407 (See Office Action, page 6, last paragraph) or withdraw this line of argument.

Applicant respectfully traverses the statements in the Office Action at page 7, last paragraph to page 8, first paragraph, “the specification has not provided any reasoning or criticality for the claimed elements and lacking such, the Examiner does not find patentable subject matter in those limitations. The systems of the prior art operate on basically the same principle and in the same manner as the Applicant’s device. Those limitations which Applicant relies on provide no novel or unexpected results and use of such limitations in lieu of those used in the references solves no stated problem and would be an obvious matter of design choice within the skill in the art.” Applicant is unaware of such standards for patentability and requests the Examiner show where such a standard is used to determine patentability.

Further, according to M.P.E.P. § 2144.04, “The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims . . . is not by itself sufficient to support a finding of obviousness. The prior art *must* provide a motivation or reason for the worker in the art, without the benefit of the [Applicant’s] specification, to make the necessary changes in the reference device.” (emphasis added) *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984). The Office Action lacks such motivation or reason. Pursuant to M.P.E.P. § 2143.01, Applicant respectfully requests the Examiner identify an objective source for the motivation to modify the applied references in the manner proposed.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 371-2117 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

BRUCE TOCKMAN ET AL.

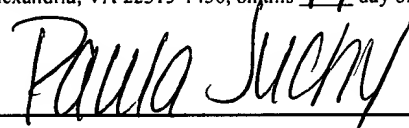
By their Representatives,

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Date 5/17/04

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of May, 2004.



Name



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